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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,718	10/17/2003	Jack D. Lemmon	M190.143.101	1756

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EXAMINER
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SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/688,718

Applicant(s)

LEMMON, JACK D.

Examiner

Bruce E Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 14, 23, 29 and 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-13, 15-22, 24-28 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/17/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 4-7, 14, 23, 29, and 31-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected Group/species. The Examiner has withdrawn claims 4-6 directed to a non-elected species. Claim 4 (stent) clearly reads on the non-elected embodiment shown in figure 2C. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/3/05.

Applicant's election with traverse in the reply filed on 3/3/05 is acknowledged. The traversal is on the ground(s) that of that the prosecution of two inventions per application does not burden the Office. This is not found persuasive; paragraphs 3 and 4 of the Restriction Requirement describe why the restriction is proper and the added invention burdens the Office with an additional search and the prosecution of additional claims to a separate invention. Additionally, the preamble and body of the claim only claim a sizer body, no heart valve has been positively claimed in at least claim 1.

Regarding the election of species, applicant election of species 8 (Figure 8 and includes Figure 2A) is noted. The Examiner notes applicant's specification clearly states, "Figure 8 is a perspective view of an alternative embodiment (page 6, lines 12)" and "another alternative embodiment (page 8, lines 8-9)".

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: annular housing (describing a sizer) and stent. It is applicant's duty to insure all claim terminology is properly supported of the specification.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 8-10, 12-13, 15-17, 19-21, 25-26 and 30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rhee (6,350,281).

Rhee teaches a flexible sizer body for evaluating a valve annulus to determine a size of a prosthetic heart valve to be sewn to the valve annulus during heart valve replacement surgery, the prosthetic heart valve including an annular extension having a first flexibility and a sewing ring having a second flexibility, the flexible sizer body comprising:

an outer ring 16 characterized by the absence of a cloth cover; and an annular wall 18 coupled to and extending from the outer ring, the annular wall having a flexibility substantially similar to the first flexibility of the annular extension of the prosthetic heart valve.

The Examiner notes that applicant has only defined the flexibility of the annular wall to be substantially similar to the flexibility of the annular extension of the heart valve, however, fails to define the flexibility of the heart valve. It is well known in the art that the flexibility of an annular extension of various heart valves can range from little flexibility (rigid) or can have a greater degree of flexibility. It is the Examiner's position that any degree of flexibility (including greater than or equal to no flexibility) would fulfill this undefined limitation. The Examiner notes claim 13 teaching the annular wall 18 is substantially rigid and claim 14 teaching the annular wall is resilient.

Regarding at least claim 8, see 3:55-58.

Regarding at least claim 4, the annular wall is interpreted as being a stent.

Regarding claim 10, wherein the outer ring and the annular wall are each at least partially formed of an elastomeric material, note 5:24-27 teaching the outer ring is ***“made from resilient material, such as a soft polymer, so as to be compressible and flexible”*** which is interpreted as being an elastomeric material. Further note, 6:58-64 teaching the annular wall can be resilient and formed as a one-piece design with the outer ring, therefore, also being an elastomeric material.

Regarding at least claim 15, the body inherently has a variable flexibility. Again, the heart valve flexibility is undefined.

Regarding claim 18, “parabolic”, the annular is interpreted as including element 14; see at least 7:1-4.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee (6,350,281).

Rhee teaches the sizer as described above, however, fails to specifically teach the outer ring and annular wall are each formed of at least one of the group consisting of santoprene, silicon, and polyurethane. Again, Rhee teaches the outer ring is ***“made from resilient material, such as a soft polymer, so as to be compressible and***

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**flexible**" which is interpreted as being an elastomeric material. Further note, 6:58-64 teaching the annular wall can be resilient and formed as a one-piece design with the outer ring, therefore, also being an elastomeric material. It would have been obvious to one having ordinary skill in the art to have selected at least one of the claimed materials because they are well known in the art for their biocompatibility and use for heart valve or sizer construction; note 6:64-67.

Regarding claim 22, Rhee appears to teach a tapered handle 12. It is known in the art to have cylindrical handles and would have been obvious to one having ordinary skill in the art to have utilized a cylindrical handle with the device of Rhee as a well known variation which is easier to manufacture. Said cylindrical handle is fully capable of meeting the functional language of sizing.

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee (6,350,281) in view of Love et al (2002/0020074).

Rhee teaches the sizer as described above, however, fails to teach the annular wall forms a plurality of extremities. Love et al teaches a sizer having the claimed configuration. It would have been obvious to one having ordinary skill in the art to have utilized the claimed configuration taught by Love et al with the annular wall of Rhee such that the sizer "correspond to the geometry of the normal valve leaflet anatomy (paragraph 5)" or by better "matching the artificial heart configuration, the sizer is able to 'mimic' more accurately how the artificial heart valve will be received in the valve annulus for sewing (4:1-4 of Rehee)".


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW  
PRIMARY EXAMINER